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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,501	12/13/2001	Charles F. Streckfus	4856-CIP	8069
32885	7590	08/25/2004		
STITES & HARBISON PLLC 424 CHURCH STREET SUITE 1800 NASHVILLE, TN 37219-2376				
			EXAMINER HOLLERAN, ANNE L	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/914,501

**Applicant(s)**

STRECKFUS ET AL.

**Examiner**

Anne Holleran

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

1. The amendment filed April 26, 2004 is acknowledged. Claim 1 was amended.
2. Claims 1-14 are pending and examined on the merits.

***New Grounds of Rejection:***

3. Claim 3 and 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 4 broadens the scope of claim 1, from which claim 4 depends. Claim 1 is drawn to a method comprising the use of salivary secretion concentrations to compare with a biomarker reference panel, whereas claim 4 is drawn to a method where the reference panel includes "value ranges". This rejection would be overcome if applicant amended claim 4 to include the word "concentration" to replace "value".

Claim 3 appears to be drawn to an invention of essentially same scope as that of claim 1, from which claim 3 depends. Applicant may overcome this objection by canceling claim 3.

4. Claims 1-9 are is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the phrase “the salivary secretion concentration” lacks antecedent basis in the claim.

Claim 5 is indefinite because of the phrase “proteinaceous expressions of said oncogene”. The specification does not define the scope of this phrase and it is not clear whether this phrase refers to a method for detecting c-erbB2 protein, fragments of the protein, splice variants of c-erbB2, or mutants of c-erbB2.

Claim 3 is indefinite because it appears to have the same scope as that of claim 1. It appears that the limitations of claim 3 were incorporated into claim 1, without cancellation of claim 3.

Claim 6 is indefinite because it is not clear how this further limits claim 1, from which claim 6 ultimately depends. Claim 6 contains the recitation “said constituent is associated with a concentration value”, and claim 1 contains the recitation “using the salivary secretion concentration of said individual biomarker”.

5. The rejection of claims 1-9 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New grounds of rejection are presented. The basis for this rejection is that

the description in the disclosure of the specification is confined to measurements of protein biomarkers in saliva, and that the measurement of protein biomarkers is not representative of methods that include within their scope the measurement of nucleic acid biomarkers.

Claim 5 is drawn to methods where the presence of at least one oncogene c-erbB-2 and proteinaceous expressions of said oncogene. Therefore, claim 5 appears to read on the measurement, in saliva, of a c-erbB-2 nucleic acid that encodes for the proteinaceous expression of the c-erbB-2 oncogene. Because claim 5 reads on measurements of nucleic acid and depends from claim 1, it appears that within the scope of claim 1 and any claims that depend from claim 1, are methods employing the use of salivary nucleic acid measurements.

The specification confines its working examples to demonstrating a correlation of breast cancer diagnosis with differences in salivary concentrations of protein cancer antigen 15-3, tumor suppressor oncogene protein 53 and the protein product of oncogene c-erbB-2 compared to samples from individuals having a benign tumor or having no tumor at all (normal). The specification also contemplates the use of measurements of cathepsin-D and epidermal growth factor receptor, but shows data demonstrating that these markers, when measured in samples of saliva, cannot be used for the detection of breast cancer. Furthermore, the specification does not provide any examples where concentrations or presence a c-erbB-2 nucleic acid in saliva are detected and correlated with a diagnosis of breast cancer.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is for purposes of the ‘written description’ inquiry, “*whatever is now claimed*” (see page 1117). The specification does not “clearly allow persons

of ordinary skill in the art to recognize that [he or she] invented what is now claimed.” (See Vas-Cath at page 1116.) Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or testing it.

In the instant case, the claimed inventions, are drawn to methods using biomarkers, the salivary concentration of which, is to be related to a diagnosis of breast cancer, where the biomarkers may be any constituent of a biomarker panel, where the panel is set forth in the claims as “including at least one of cancer antigens 15-3, tumor suppressor oncogene protein 53 and oncogene c-erbB-2”. The breadth of the claimed inventions are not supported by the disclosure of the specification, because the disclosure teaches that salivary concentration measurements of proteins, those of cancer antigen 15-3, tumor suppressor oncogene protein 53 and the protein product of oncogene c-erbB-2 are useful in the diagnosis, whereas salivary concentration measurements of cathepsin D and epidermal growth factor receptor are not. Therefore, it does not appear that any known cancer antigen is useful for the claimed methods and that reduction to practice must occur for applicant to be in possession of methods using biomarkers other than cancer antigens 15-3, tumor suppressor oncogene protein 53 and the protein product of oncogene c-erbB-2. Similarly, the specification fails to describe a correlation between measurements, in saliva, of nucleic acids encoding c-erbB-2 or any other biomarker and a diagnosis of breast cancer. Because such measurements in saliva do not appear to be known in the art and because the specification provides no working examples to assess whether a correlation in salivary protein measurements may be extrapolated to salivary nucleic acid measurements, applicant does not appear to be in possession of the claimed methods.

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***Conclusion***


Claims 1-9 are rejected. Claims 10-14 are allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran  
Patent Examiner  
August 23, 2004



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER